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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Szu-Min Lin

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EXAMINER

CHORBAJI, MONZER R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/646,296	Applicant(s) LIN ET AL.	
	Examiner MONZER R. CHORBAJI	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/28/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This final action is in response to the RCE/amendment received on 2/6/08

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 and 9-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cummings (EP 0 373 201 B1).

Regarding claim 1, Cummings discloses a vapor hydrogen peroxide sterilization method for treating medical items (page 2, lines 45-50) that includes the following: placing articles into the chamber (page 2, lines 47-48), reducing pressure in the chamber to a first pressure that is above hydrogen peroxide vapor pressure and below atmospheric pressure (page 4, lines 24-27), introducing a sterilant as a mist (mist or vapor are synonyms of one another) into the chamber (page 5, lines 35-42), and diffusing the mist through the chamber into contact with the articles (page 5, 28-31). As to the limitation of enhancing the diffusion of the mist throughout the chamber by reducing the first pressure to a value below atmospheric pressure and above the sterilant vapor pressure, Cummings as explained above apply the vacuum step as claimed and the claimed subject matter is therefore inherent in the Cummings reference as

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explained in MPEP 2112, II where inherent feature need not be recognized at the time of the invention.

Regarding claim 11, Cummings discloses a method of sterilizing an article (page 2, lines 45-50 where contaminating specimens are considered articles) comprising: placing the article into a chamber (page 2, lines 47-48); and reducing pressure in the chamber to a first pressure (page 5, lines 29-32) then introducing hydrogen peroxide vapor (page 5, lines 36-38) into the sterilization chamber. As to the limitation of reducing the pressure in the chamber to a first value to disperse a mist (mist or vapor are synonyms of one another) comprising a sterilant throughout the chamber and into contact with the article, Cummings as explained above apply the vacuum step as claimed and the claimed subject matter is therefore inherent in the Cummings reference as explained in MPEP 2112, II where inherent feature need not be recognized at the time of the invention.

Regarding claims 2-3 and 14-15, Cummings discloses generating vapor hydrogen peroxide from a solution of hydrogen peroxide and water (page 4, lines 24-41).

Regarding claims 4-6, Cummings teaches that the first vacuum pressure is at least 5 Torr, or 15 Torr, or 30 Torr below atmospheric (page 4, lines 24-27, the mm Hg unit in Cummings is equivalent to the Torr unit and 1 atmosphere is equal to 760 mm Hg or 760 Torr. For example, 5 mm Hg vacuum is below 5 Torr, or 15 Torr, or 30 Torr below atmospheric pressure).

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Regarding claims 16-18, Cummings teaches that the first vacuum pressure is at least 5 Torr, or 15 Torr, or 30 Torr below atmospheric (page 5, lines 28-30, the mm Hg unit in Cummings is equivalent to the Torr unit and 1 atmosphere is equal to 760 mm Hg or 760 Torr where 0.3 mm Hg vacuum is below 5 Torr, or 15 Torr, or 30 Torr below atmospheric pressure).

Regarding claims 7 and 9-10, Cummings teaches the following: sterilizing articles (page 2, lines 45-50), sterilizing the interior of the chamber (page 5, lines 54-56) and removing residual hydrogen peroxide from the chamber (page 6, lines 5-9).

Regarding claims 12-13, Cummings teaches reducing occurs prior (page 5, lines 28-30) to admission of the mist (page 5, lines 36-38) into the chamber where the reducing occurs using a vacuum (page 5, lines 28-29).

Regarding claims 19-20, Cummings teaches that once a vacuum is established (page 5, lines 33-34), the mist is admitted into the chamber (page 5, lines 36-38) and that the first pressure is a negative pressure (page 5, line 30).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings (EP 0 373 201 B1) as applied to claim 7 and further in view of Jacobs et al (U.S.P.N. 5,785,934).

Cummings tests the efficacy of the vapor hydrogen peroxide sterilization method by inoculating coupons with 10^6 *Bacillus stearothermophilus* (pages 6-7) prior to sterilization. Cummings further teaches sterilization cycles of 4 or 8 or 16 minutes (page 7). However, Cummings fails to teach inoculating stainless steel

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blades with 10^6 *Bacillus stearothermophilus*. Jacobs teaches inoculating stainless steel scalpel blades with *Bacillus stearothermophilus* (col.30, lines 49-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Cummings testing method by adding 10^6 *Bacillus stearothermophilus* inoculated stainless steel blades as taught by Jacobs in order to guarantee the sterility of surgical devices so that no post-surgery infections occur.

Response to Arguments

7. Applicant's arguments filed on 02/06/2008 have been fully considered but they are not persuasive.

On page 6 of the Remarks section, Applicant argues that Cummings fails to teach reducing pressure in the chamber to a first pressure wherein the first pressure is below atmospheric pressure (i.e., 760 mm Hg) and above the vapor pressure of the sterilant whereby to enhance diffusion of the mist throughout the chamber, as recited in claim 1; that instead Cummings teaches reducing the absolute chamber pressure above the vapor pressure of hydrogen peroxide and below the vapor pressure of water to promote the evaporation water and control the evaporation of the condensate; and that the pressure conditions taught by Cummings are meant to satisfy a clearly stated objective

Cummings discloses a vapor hydrogen peroxide sterilization method for treating medical items that includes reducing pressure in the chamber to a first pressure that is above hydrogen peroxide vapor pressure and below atmospheric pressure (page 4, lines 24-27). For example, a 5 mm Hg vacuum that falls within

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the disclosed range on page 4, line 27, is below atmospheric pressure, which is equal to 760 mm Hg. As to the limitation of enhancing the diffusion of the mist throughout the chamber by reducing the first pressure to a value below atmospheric pressure and above the sterilant vapor pressure, Cummings as explained above apply the vacuum step as claimed and the claimed subject matter is therefore inherent in the Cummings reference as explained in MPEP 2112, II where inherent feature need not be recognized at the time of the invention. As such one of ordinary skill in the art would recognize upon reading the Cummings reference, that both the instant claims and the reference are performing the same steps where Cummings method is inherently enhancing the diffusion of the mist throughout the chamber.

On page 7 of the Remarks section, Applicant argues that in Applicant's claimed method, a significantly greater pressure (such as set forth in claims 4-6) is employed when compared to the Cummings system in order to enhance the diffusion of the mist throughout the chamber; that Cummings specifically teaches a conventional delivery system wherein hydrogen peroxide diffuses through the chamber through continued injection of vapor phase hydrogen peroxide to establish a flow-through system.

Cummings teaches that the first vacuum pressure is at least 5 Torr, or 15 Torr, or 30 Torr below atmospheric (page 4, lines 24-27, the mm Hg unit in Cummings is equivalent to the Torr unit and 1 atmosphere is equal to 760 mm Hg or 760 Torr. For example, 5 mm Hg vacuum hat falls within the disclosed range on page 4, line 27, is below 5 Torr, or 15 Torr, or 30 Torr below

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atmospheric pressure). The instant claims recite that the pressures are at least so many torr below atmospheric pressure. If applicant intends to argue the significance of a high vacuum pressure, then applicant should recite specific pressures. At least so many torr below is only a minimum. No upper limit distinguishing the vacuum pressure from the prior art has been set forth. Furthermore, the instant claims do not preclude the continuous injection of vapor phase hydrogen peroxide to establish a flow-through system.

Conclusion

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. R. C./

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797